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09/771,382	01/25/2001	Ian Richard Anselm Peak	8795-24 U1	6450

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EXAMINER	
FORD, VANESSA L	
ART UNIT	**PAPER NUMBER**
1645	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/771,382	PEAK ET AL.	
	Examiner	Art Unit	
	Vanessa L. Ford	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *33,34 and 49-58* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *33,34 and 49-52* is/are allowed.

6)☒ Claim(s) *53-58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 June 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 11, 2006 has been entered.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in the prior Office Action.

Rejections Withdrawn

3. In view of Applicant's amendment and remarks the following rejections are withdrawn.

a) rejection of claims 53-58 under U.S.C. 102(a), pages 9-10, paragraph 5.7

b) rejection of claims 53-58 under U.S.C. 102(a), pages 10-11, paragraph 6.

b) rejection of claims 53-58 under U.S.C. 102(e), pages 11-12, paragraph 7.

Rejections Maintained

4. The rejection under 35 U.S.C. 112, first paragraph (enablement) is maintained for newly submitted claims 53-58 for the reasons set forth on pages 3-8, paragraph 4 of the Final Office Action.

The rejection was on the grounds that the claims 53-58 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for isolated proteins as set forth in SEQ ID NOs: 23 and 35 and compositions comprising the isolated proteins, does not reasonably provide enablement for proteins that are variants of SEQ ID NOs: 23 or 35 or compositions comprising these proteins. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The instant specification broadly discloses a genus of polypeptides that comprises SEQ ID NO:23 and SEQ ID NO:35. The instant specification teaches that SEQ ID NO: 23 is the amino acid sequence of a PMC 21 NhhA deletion mutant polypeptide (page 8 and Example 4). The instant specification teaches that SEQ ID NO: 35 is the amino acid sequence of a predicted mature protein described in Example 4 (page 10 and Example 4). The instant specification teaches that recombinant DNA-based production of the polypeptides of the invention can be accomplished by the deletion of one or a few amino acids of the (conserved) C1, C2, C3, C4 and/or C5 or (variable) V1, V2, V3 and/or V4 regions of the consensus polypeptide (SEQ ID NO:11) (page 13). The specification teaches that SEQ ID NO:11 comprises constant regions of NhhA polypeptide designated as C1-C5 and non-conserved regions designated as V1-V-4 (page 3). The instant specification teaches that V1-V4 are non-conserved amino acids of a variable region (page 3). Therefore, the non-conserved regions of SEQ ID NO:11 can comprise any amino acid. Thus, the claimed polypeptide as set forth in SEQ ID NO:11 as well as variants of SEQ ID NOs. 23 and 35 can include any substitution or change of amino acids throughout regions V1-V4 of the polypeptide sequence. Therefore, SEQ ID No: 11 and variant or fragments of SEQ ID NOs: 23 and 35 can correspond to mutated sequences, allelic variants, splice variants, sequences that have a variant degree of identity (similarity, homology), and so forth are being claimed. There is no guidance provided as to which amino acids can be substituted, inserted or deleted and the polypeptide would retain its biological function. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of polypeptides broadly encompassed by the claims and the claims broadly encompass a significant number of inoperative species. Since the amino acid sequence of the polypeptide determines its structural and functional properties, predictability of which changes can be tolerated in a polypeptide's amino acid sequence and still retain similar activity/utility requires a knowledge with regard to which amino

acids in the polypeptide's sequence, if any, are tolerant of modification and which are conserved (i.e. expected intolerant to modification) and detailed knowledge of the ways in which the polypeptide's structure relates to function. However, the problem of the prediction of polypeptide structure from mere sequence data of a single polypeptide and in turn utilizing predicted structural determinations to ascertain functional aspects of the polypeptide and finally what changes can be tolerated with respect thereto is extremely complex and outside of the realm of routine experimentation. There is no guidance as to what amino acids may not be changed without causing a detrimental effect to the polypeptide being claimed. The claims broadly teach polypeptides, which include substitutions and/or deletions, therefore any polypeptide is being claimed, and no specific location for the deletion, substitution or any combination thereof is recited. Thus, the resulting polypeptide could result in a polypeptide not taught nor enabled by the specification.

The claims of the instant application are not only drawn to isolated proteins but are also drawn to isolated proteins that have at least 80% or at least 90% identity to SEQ ID NOs. 23 and 35. Thus, the claimed isolated proteins include variants as well as fragments of SEQ ID NOs 23 and 35. There is no guidance provided in the specification as how one would begin to choose " variants or fragments" of SEQ ID NOs: 23 or 35. The specification does not support the broad scope of the claims, which encompass all modifications and fragments because the specification does not disclose the following:

- the general tolerance to modification and extent of such tolerance;
- specific positions and regions of sequence(s) which can be predictably modified and which regions are critical;
- what fragments, if any, can be made which the retain the biological activity if the intact protein; and
- the specification provide essentially no guidance as to which of the essentially infinite possible choice is likely to be successful.

Thomas E. Creighton, in his book, "*Proteins: Structures and Molecular Properties, 1984*", (pages 314-315) teaches that variation of the primary structure of a protein can result in an instable molecule. He teaches that a single amino acid change can cause a mutant hemoglobin to have lower stabilities due to any of several causes: 1) alteration of close-packing of the interior; loss of one group that normally participates in a hydrogen bond or salt bridge; 2) the introduction of a charged or polar group into the interior or the insertion into a helical region of a Praline residue, which must distort the alpha-helix; 3) while sometimes radical changes of surface groups, even introduction of a non-polar side chain- have no great effect on stability.

Thomas E. Creighton, in his book "*Protein Structure: A Practical Approach, 1989; pages 184-186*" teaches that present day site directed mutagenesis of a gene allows any amino acids in a protein sequence to be changed to any other, as well as introducing deletions and insertions". The reference goes on to teach that it is difficult to know which amino acid to change and which is the best residue to substitute for the desired functional and structural effect.

Nosoh, Y. et al in "*Protein Stability and Stabilization through Protein Engineering, 1991" (chapter 7, page 197, second paragraph)* adds support to Thomas E. Creighton,

by teaching that results so far accumulated on the stability and stabilization of proteins appear to indicate that the strategy for stabilizing proteins differ from protein to protein and that any generalized mechanisms for protein stability have not yet been presented.

Factors to be considered in determining whether undue experimentation is required, are set forth in In re Wands 8 USPQ2d 1400. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and (8) the breadth of the claims.

Therefore, the specification fails to provide guidance regarding how to make and use polypeptides that fall within the broadly claimed genus of SEQ ID NO:11 that retain the claimed activity as well as how to make and use variants or fragments of SEQ ID NOs: 23 and 35.

Applying the above test to the facts of record, it is determined that 1) no declaration under 37 C.F.R. 1.132 or other relevant evidence has been made of record establishing the amount of experimentation necessary, 2) insufficient direction or guidance is presented in the specification with respect to selecting polypeptides that fall within the broadly claimed genus of variants or fragments of SEQ ID NOs: 23 and 35 having claimed functional features, 3) the relative skill of those in the art is commonly recognized as quite high (post-doctoral level). One of skill in the art would require guidance, in order to make or use polypeptides that are fall within the broadly claimed genus variants or fragments of SEQ ID NOs: 23 and 35 in a manner reasonable in correlation with the scope of the claims. Without proper guidance, the experimentation is undue.

Applicants Arguments:

A) Applicant urges that the specification teach how to make and use variants of SEQ ID Nos: 23 and 25. Applicant provides a table that show the level of sequence identity between SEQ ID Nos: 23 and 35. Applicant urges that a large number of sequences can be made that have 80% or 90% sequence identity to SEQ ID NOS:23 or 35 by replacing , deleting or shuffling V and/or C regions with a view to creating a protein that elicits a more cross-protective immune response.

B) Applicant urges that Figure 1 of the instant specification indicates residue by residue for each of SEQ ID Nos:1-10, in some cases a limited set of

variations occurs between SEQ ID Nos:1-10 or in some cases a more extensive set of variations occurs between SEQ ID Nos: 1-10 and in some cases certain residues may be present or absent between SEQ ID Nos:1-10. Applicant urges that the specification provides an adequate representative number of species of genus of proteins encompassed by claimed 53-58.

Examiner's Response to Applicant's Arguments:

A) It is the Examiner's position that claims 53-58 do not comply with 35 U.S.C. 112, first paragraph. Applicant has shown how to make and use SEQ ID Nos: 23 and 35 but has not shown how to make variants of the polypeptide as set forth in SEQ ID Nos:23 and 35 that possesses the recited function of eliciting an immune response in a plurality of *N. meningitides* strains. It should be remembered that the statute under 35 U.S.C. 112, first paragraph requires that Applicant teach how to make and use the claimed invention and not how to find variants of SEQ ID NO:23 and SEQ ID NO:35. One of skill in the art would not conclude that Applicant has enabled polypeptides that are variants of SEQ ID NOs: 23 and 35 based on what is disclosed in the instant specification.

B) It should be noted that SEQ ID Nos: 23 and 35 are two species of the genus of polypeptides represented by SEQ ID NO: 11. To address Applicant comments regarding Figure 1 and Table I of the instant specification, the figure and table merely

disclose the conserved regions and variable regions which are used to generate a consensus sequence from 10 strains of *N. meningitidis* strains. These conservative sequences are set forth in forth in SEQ ID NO:11. Figure 1 and Table 1 in no way convey which amino acids are modified along the amino acid sequence as set forth in SEQ ID NO:23 or SEQ ID NO:35 nor do Figure 1 or Table 1 convey what positions are modified along the amino acid sequence as set forth in SEQ ID NO:23 or SEQ ID NO:35 to arrive at variant polypeptides that have the same or similarly functional properties as the polypeptides set forth in SEQ ID NOs:23 and 35 and the claims. In other words, the instant specification has not shown how to make variants of SEQ ID Nos: 23 and 35 that have the claimed function of eliciting an immune response in a plurality of *N. meningitides* strains.

Applicant has not correlated a structure of the claimed variants (polypeptides with 80 or 90% identity to SEQ ID Nos: 23 or 35) with the recited function (capable of eliciting an immune response to a plurality of strains of *N. meningitides)* for the claimed genus of polypeptides encompassed by the claimed invention.

The specification is silent as to which specific "immunoepitopes " or "immunogenic fragments" or "variants" confers a given immune response to a plurality of *Neisseria meningitides* strains. Given the lack of guidance contained in the specification and the unpredictability in determining acceptable sequence variations, one of skill in the art could not make the broadly claimed invention without undue experimentation. Protein chemistry is probably one of the most unpredictable areas of biotechnology. The effects of sequence dissimilarities upon protein structure and

function cannot be predicted. Bowie et al (*Science, 1990, 257:1306-1310)* teach that an amino acid sequence encodes a message that determines the shape and function of a protein and that it is the ability of these proteins to fold into unique three-dimensional structures that allows them to function, carry out the instructions of the genome and form immunoepitopes. Bowie et al. further teach that the problem of predicting protein structure from sequence data and in turn utilizing predicted structural determinations to ascertain functional aspects of the protein is extremely complex. (column 1, page 1306). Bowie et al further teach that while it is known that many amino acid substitutions are possible in any given protein, the position within the protein's sequence where such amino acid substitutions can be made with a reasonable expectation of maintaining function are limited. Certain positions in the sequence are critical to the three dimensional structure/function relationship and these regions can tolerate only conservative substitutions or no substitutions (column 2, page 1306). Additionally, Greenspan et al. (*Nature Biotechnology 17: 936-937, 1999),* disclose defining epitopes is not as easy as it seems. Greenspan et al. recommends defining an epitope by the structural characterization of the molecular interface between the antigen and the antibody is necessary to define an "epitope" (page 937, column 2). According to Greenspan et al., an epitope will include residues that make contacts with a ligand, here the antibody, but are energetically neutral, or even destabilizing to binding. Furthermore, an epitope will not include any residue not contacted by the antibody, even though substitution of such a residue might profoundly affect binding. Accordingly, it follows that the immunoepitopes that can elicit an immune response to a given

pathogen can only be identified empirically. This constitutes undue experimentation. Therefore, given the lack of success in the art, the lack of working examples commensurate in scope to the claimed invention and the unpredictability of the generation of a directed immune response, the specification, as filed, is not enabled for the full breath of the claimed invention.

In view of all of the above this rejection is maintain because applicant has not describe specific immunoepitopes are required in the claimed immunogenic variants (e.g. polypeptides that have 80% or 90% identity to SEQ ID NOS: 23 or 35) that can are capable of eliciting an immune response to a plurality of strains of *N. meningitides*.

Applicant has not meet the burden required under 35 U.S.C. 112, first paragraph.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 53-58 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *This is a new matter rejection.* The amendment filed August 15, 2005 introduces new matter into the claims.

35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. Applicant's amendment introduces "new matter" that is not supported by the original disclosure. The specification fails to disclose the recited claim limitation "an isolated protein the entire amino acid sequence of which has at least 80% sequence identity to the entire amino acid sequence set forth in SEQ ID NO:35 wherein the isolated protein is not a full length NhhA polypeptide and is capable of eliciting an immune response to a plurality of strain of *N. meningitides*" or the claim limitation an isolated protein the entire amino acid sequence of which has at least 90% sequence identity to the entire amino acid sequence set forth in SEQ ID NO: 23 or SEQ ID NO:35 wherein the isolated protein is not a full length NhhA polypeptide and is capable of eliciting an immune response to a plurality of strain of *N. meningitides*". Applicant has directed the Examiner to page 3, lines 1-6 of the instant specification. Page 3 of the specification states " proteins of the invention may therefore have one or more deletions of non-conserved amino acids compared to a corresponding wild-type NhhA polypeptide". This statement merely means that the polypeptides of the inventions are polypeptides that have sequences that are less than that of the wild-type NhhA protein. The Examiner has reviewed the instant specification and has failed to find the support for the amendment which recites the claim limitations "...at least 80% sequence identity to the entire amino acid sequence set forth in SEQ ID NO:35 wherein the isolated protein is ***not a full length NhhA polypeptide*** and is capable of eliciting an immune response to a plurality of strain of *N. meningitides*" or the claim limitation an isolated protein the entire amino acid sequence of which has at least 90% sequence identity to

the entire amino acid sequence set forth in SEQ ID NO: 23 or SEQ ID NO:35 wherein the isolated protein is ***not a full length NhhA polypeptide*** and is capable of eliciting an immune response to a plurality of strain of *N. meningitides".* Applicant is required to cancel the new matter in the reply to this Office Action.

6. Claims 53-58 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. *This is a written description rejection.*

The specification broadly describes as an isolated protein the entire amino acid sequence of which has at least 80% sequence identity to the entire amino acid sequence set forth in SEQ ID NO:35 wherein the isolated protein is not a full length NhhA polypeptide and is capable of eliciting an immune response to a plurality of strain of *N. meningitides"* or the claim limitation an isolated protein the entire amino acid sequence of which has at least 90% sequence identity to the entire amino acid sequence set forth in SEQ ID NO: 23 or SEQ ID NO:35 wherein the isolated protein is not a full length NhhA polypeptide and is capable of eliciting an immune response to a plurality of strain of *N. meningitides".*

The specification teaches proteins of the invention may therefore have one or more deletions of non-conserved amino acids compared to a corresponding wild-type NhhA polypeptide (page 3). The specification also teaches that polypeptides homologs share at least 70%, preferably 80% and more preferably at least 90% identity with the

amino acid sequences of modified NhhA polypeptides of the invention (page 15). However, the instant specification has failed to teach or disclose isolates proteins that have at least 80% identity to SEQ NO:35 wherein the isolated protein is not a full length NhhA polypeptide and is capable of eliciting an immune response to a plurality of strains *N. meningitides"* or isolated proteins that have at least 90% identity to SEQ ID Nos: 23 and 35 wherein the isolated protein is not a full length NhhA polypeptide and is capable of eliciting an immune response to a plurality of strains *N. meningitides".*

Thus, the instant specification lacks written description for the claimed invention.

Therefore, claimed invention fails to meet the written description provision of 35 U.S.C. 112, first, paragraph. The specification provides insufficient written description to support the genus encompassed by the claim.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

The skilled artisan cannot envision the detailed chemical structure of the encompassed polypeptide regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai

Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Therefore, the instant specification does not provide written description for the full breadth of the claim. Thus the broadly claimed invention does not meet the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 53 recites the claim limitation "...full length NhhA polypeptide. What does Applicant mean by this phrase? Is Applicant referring to the wild-type NhhA from *N. meningitides*? Correction is required.

Status of Claims

8. Claims 33-34 and 49-58 appear to be free of the cited prior art. The closet prior art, Peak et al *(WO 99/31132 published June 24, 1999)* or Peak et al *(U.S. Patent No. 6,197, 312 B1 published March 2001)* or Masignani et al *(WO 99/36544 published July 22, 1999)* do not teach or disclose an isolated protein having the amino acid sequence SEQ ID NO:23 or a mature processed form of the isolated protein having the amino acid sequence of SEQ ID NO:35. Peak et al *WO 99/31132 published June 24, 1999)* or Peak et al *(U.S. Patent No. 6,197, 312 B1 published March 200)1* nor Masignani et al teach polypeptides that have at least 80% sequence identity to the entire amino acid sequence set forth in SEQ ID NO:35 wherein the isolated protein is not a full length NhhA polypeptide and is capable of eliciting an immune response to a plurality of strain of N. meningitides" or the claim limitation an isolated protein the entire amino acid sequence of which has at least 90% sequence identity to the entire amino acid sequence set forth in SEQ ID NO: 23 or SEQ ID NO:35 wherein the isolated protein is not a full length NhhA polypeptide and is capable of eliciting an immune response to a plurality of strain of *N. meningitides".* The prior art also do not teach compositions comprising these polypeptides.

Conclusion

9. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308–0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 872-9306.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (571) 272-0857. The examiner can normally be reached on Monday – Friday from 9:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffery Siew, can be reached at (571) 272-0787.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov./>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vanessa L. Ford
Biotechnology Patent Examiner
February 28, 2007

NITA MINNIFIELD
PRIMARY EXAMINER